DEPARTMENT OF HEALTH AND HUMAN SERVICES

Our Reference No.: 99-1390

FEB 0 9 2000

Robert L. Garnick, Ph.D.
Genentech, Inc.
1 DNA Way
South San Francisco, CA 94080-4990

Dear Dr. Garnick:

Your request to supplement your biologics license application for Trastuzumab to include proposed label changes to the package insert, product container, and package to clarify the instructions for reconstitution, has been approved.

We acknowledge your written commitment of February 3, 2000, to develop a 20 mL diluent vial to be packaged with this product. We understand that the first lot will be filled and placed on stability by March 2000.

Please submit final printed labeling at the time of use and include implementation information on FDA Form 2567. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

This information will be included in your biologics license application file.

Sincerely yours,

Kathryn E. Stein, Ph.D.
Director
Division of Monoclonal Antibodies
Office of Therapeutics
Research and Review
Center for Biologics
Evaluation and Research